

REMARKS

Claims 19-33 are pending in the application. Claims 30 and 31 are allowed. Claims 19-29, 32 and 33 are currently under consideration.

Claim Objections

The Examiner has noted that claims 26 and 29 contain typographical errors. Claim 29 has been amended to correct the error. Regarding claim 26, Applicants note that "foliate" is the correct spelling of the term (see specification p. 8, l. 10).

Rejections under 35 USC § 112, first paragraph

Claims 19-29, 32 and 33 have been rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification, while being enabling for nuclide activation therapy(NAT) agents selected from the group consisting of o-carboranylalanine $B_{10}C_2H_2CH_2-CHCO_2NH_2$, carborane butamine $B_{10}C_2H_2-(CH_3)_3CHCO_2NH_2$, p-boronophenylalanine, $B_{12}H_{11}SH$, mercaptoundecahydrododecacarborate, boronated porphyrins, $B_{12}H_{11}SH$ glutathione disulfide, and water soluble tetracarbonylphenylporphyrin, does not reasonably provide enablement for all NATs. The examiner asserted that the specification does not enable one of skill in the art to make and use the invention commensurate in scope with the claims. This rejection is traversed. Applicants disagree with the Examiner's position, but, in the interest of expediting prosecution, have amended claim 19 to replace the nuclide activation therapy agent with the neutron capture therapy agent of claim 23. Consequently, claim 23 has been canceled. Claims 24, 26 and 27 have also been amended to reflect the change to claims 19.

Neutron capture therapy agents are well known in the art and have been studied at least since 1936 (specification p. 1, ll 6-15). Furthermore, the specification teaches in detail the principles of neutron capture therapy. Therefore, persons of skill in the art would know, based on their own knowledge of this technology and the teachings of the specification, what neutron capture therapy agent is and how to make and use it in a manner that is commensurate in scope to the claimed subject matter. Therefore, this rejection has been obviated and should be withdrawn.

Claims 19-29, 32 and 33 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description rejection. The Examiner argues that the specification does not sufficiently describe the claimed subject matter as it relates to the nuclide activation therapy agents, specifically, the modified carborane cage, the boron containing nucleic acid precursor, the boron containing foliate growth factor, the hormone, the radiation sensitizer, phosphates, phosphonates, phosphoramidates, barbiturate and cyclic thiourea derivative.

As discussed above, the claims have been amended to refer to neutron capture therapy agents, which are well known in the art. Furthermore, the specification teaches the use of these specific agents on pp. 7-8 and notes that they are known in the art. Therefore, one of skill in the art would know how the species identified above relate to the neutron capture therapy agent. As such, this rejection has been obviated and should be withdrawn.

Rejections under 35 USC § 112, second paragraph

Claims 19-29, 32 and 33 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner argues that claims 19-25, 27-29, 32 and 33 are ambiguous because it is unclear what nuclide activation therapy agent Applicant is referring to that is compatible with the instant invention. Applicants disagree with the Examiner's position, but, in the interest of expediting prosecution, have amended claim 19 to replace the nuclide activation therapy agent with the neutron capture therapy agent of claim 23. Consequently, claim 23 has been canceled. Claims 24 and 27 have also been amended to reflect the change to claims 19. As discussed above, neutron capture therapy agents are well known in the art and the specification teaches in detail the principles of neutron capture therapy. Therefore, persons of skill in the art would know, based on their own knowledge of this technology and the teachings of the specification, what neutron capture therapy agent is and how to apply such an agent to the subject matter of the present claims. Therefore, this rejection has been obviated and should be withdrawn.

The Examiner argues that claim 26 is ambiguous because of the terms: modified carborane cage, boron containing nucleic acid precursor, hormone, radiation sensitizer, phosphates, phosphonates, phosphoramidates, and cyclic thiourea derivatives. Specifically, the Examiner argues that the claims are ambiguous because it is unclear what modified, precursors, sensitizers,

derivatives, etc. are compatible with the instant invention. However, these terms are well known chemical terminology and one of skill in the art would clearly understand them. Furthermore, one of skill in the art would know how the presently claimed species can be manipulated according to these terms. Therefore, this rejection should be withdrawn.

The Examiner argues that claims 21, 28 and 29 are indefinite because they contain a broad range or limitation together with a narrow limitation that falls within the broad range or limitation since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The Examiner argues further that inclusion of the term "preferably" raises doubt as to whether the feature introduced by such language is exemplary of the remainder of the claim or a required feature of the claim. These claims have been amended to remove the "preferably" limitation and, therefore, these rejections have been obviated and should be withdrawn. Although not rejected by the Examiner, claim 27 has been similarly amended.

The Examiner argues that claim 24 is ambiguous because of the phrase "in sufficient quantity to undergo a neutron capture reaction." Specifically, the Examiner argues that it is unclear what is a "sufficient" quantity. Applicants disagree with the Examiners position that the definition of "sufficient" is variable because it is a subjective term. Applicants note however, that even if individuals have differing views on what "sufficient" requires, the specific consequence of a neutron capture reaction is required by the claims, and the occurrence of this event is not subjective - it either occurs or it does not. Furthermore, the specification (pp. 7-8) teaches the use of the

neutron capture therapy agent and the neutron capture reaction. Persons of skill in the art would know, based on the teaching of the specification and their own knowledge of this technology, how much nuclide to use so that a neutron capture reaction can occur. As such, the construction of claim 24 is clear and this rejection should be withdrawn.

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